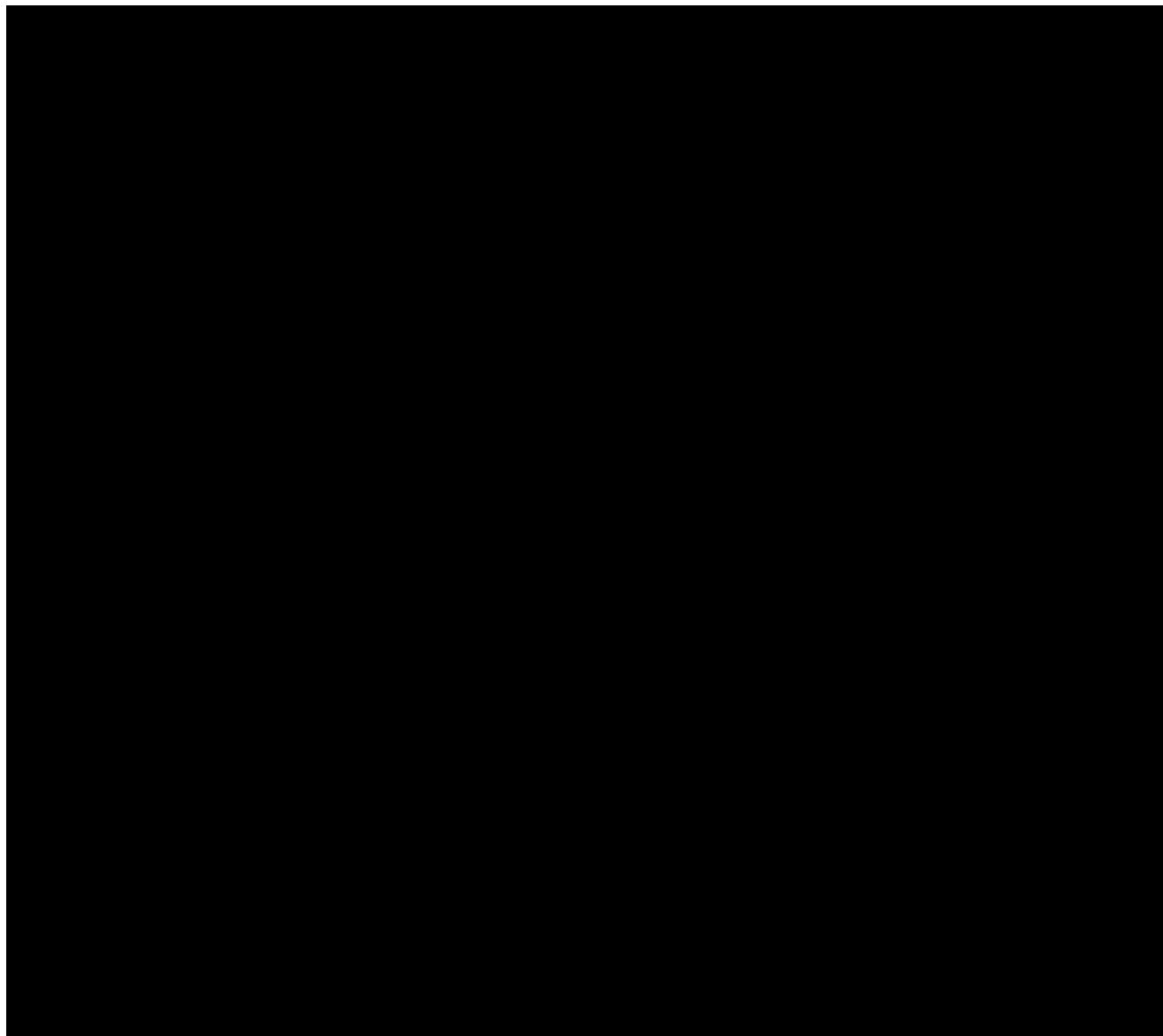


EXHIBIT

AI

APPENDIX L-3—U.S. PATENT NO. 12,048,692 INFRINGEMENT CONTENTIONS

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E.	Direct infringement.....	19
1.	Element 1[a]: "A method for treating chronic obstructive pulmonary disease (COPD) in a patient with severe to very severe COPD, the method comprising:"	20
2.	Element 1[b]: "selecting a patient having a percent predicted force expiratory volume in one second less than about 50 percent; and"	23
3.	Element 1[c]: "administering a pharmaceutical composition comprising an aqueous solution of refefenacin or a pharmaceutically acceptable salt thereof to a selected patient using a nebulizer;"	26
4.	Element 1[d]: "wherein the patient has a low peak inspiratory flow rate."	28
5.	Element 2[a]: "The method of claim 1,"	33
6.	Element 2[b]: "wherein the low peak inspiratory flow rate is less than about 50 L/min."	33
7.	Element 3[a]: "The method of claim 1,"	33
8.	Element 3[b]: "wherein the patient has a percent predicted force expiratory volume in one second less than about 40 percent."	34
9.	Element 4[a]: "The method of claim 1,"	34
10.	Element 4[b]: "wherein the patient has very severe COPD."	34



4. Element 1[d]: “wherein the patient has a low peak inspiratory flow rate.”

As discussed above, at least some HCPs will select COPD patients for treatment with Mankind’s ANDA product based on the patient having an FEV₁ of less than about 50%, and, as discussed below, at least a subset of those patients will have a low peak inspiratory flow rate (PIFR). The phrase “low peak inspiratory flow rate” is defined in the specification as “a peak inspiratory flow rate less than about 60 L/min.” (’692 patent at 4:22-23).